ATTACHMENT 9-3

PATIENT LABELING / RECONSTRUCTION

MAKING AN INFORMED DECISION

SILICONE-FILLED BREAST IMPLANT RECONSTRUCTION

INAMED
AESTHETICS

INTRODUCTION

TO THE PATIENT

The information contained in this booklet, *Making an Informed Decision, Silicone-filled Breast Implant Surgery,* is designed to provide you with an understanding of the risks and benefits of surgery with silicone filled breast implants as well as provide an overview of the experience of patients in the INAMED Core Clinical Study.

Please review this information to ensure your preoperative consultation is effective and comprehensive. Make notes about issues that you would like to further discuss with your plastic surgeon, and ask questions. Give yourself time to consider your choices and proceed with surgery only after you are satisfied that the decision is right for you.

TO THE HEALTHCARE PROFESSIONAL

Discussion of the content of this document is an important part of the informed decision making process for the patient. Please take time to familiarize yourself with the information presented here and incorporate it into your pre-operative discussion.

For your convenience a signature block is provided as a means of documenting the preoperative discussion in the patient's file.

After removing the signature block, please give this book to the patient for her records.

Making an Informed Decision

Silicone Filled Breast Implant surgery

Reconstruction

I have reviewed the information presented in *Making an Informed Decision Silicone Filled Breast Implant Surgery, Reconstruction.* My concerns and questions have been addressed by my doctor and I have considered alternatives to reconstruction surgery including use of external prostheses or surgery with saline-filled breast implants.

I am choosing to proceed with silicone filled breast implant surgery.

Patient Name

Patient Signature

Date

Surgeon Name

Surgeon Signature

Date

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SO, YOU'RE CONSIDERING SILICONE-FILLED BREAST IMPLANT SURGERY

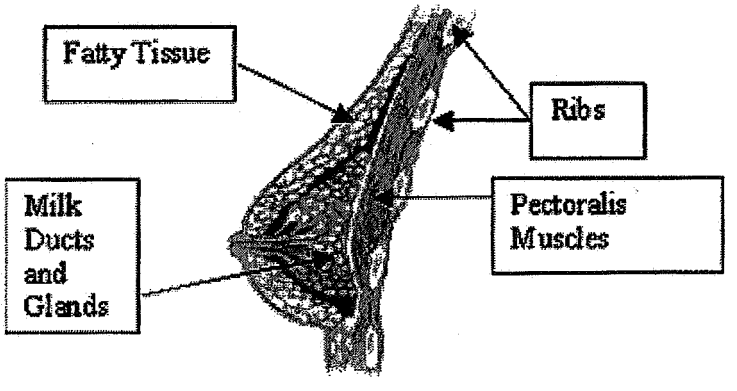
You may be considering breast implant surgery to restore your breast shape after a mastectomy or an injury that resulted in either partial or total loss of the breast(s) or to correct a birth defect. This is referred to as breast reconstruction. Whether you decide to have breast reconstruction depends on your own individual case, medical condition, general health, lifestyle, emotional state, and breast size and shape. You may wish to speak with your family, friends, breast implant support groups, and breast cancer support groups to help you in making this decision.

If you are considering breast reconstruction and do not have a plastic surgeon, ask your general surgeon for a referral for the names of experienced, board certified plastic surgeons in your area. Your general surgeon, plastic surgeon, and oncologist should work together to plan your mastectomy and reconstruction procedure to give you the best possible result.

INAMED has prepared this patient information booklet to help you better understand the breast implant procedure and assist you in making an informed decision about breast reconstruction surgery. It will help to answer some of the questions you may have about the surgery and about breast implants in general. It will also provide you with specific information about the INAMED silicone-filled breast implant product line.

This educational booklet can not and should not take the place of discussing your surgery with your plastic surgeon. Make sure to speak with your surgeon about your expectations of the results, as well as what you can expect regarding the length of the surgery, your recovery, and any potential complications of the surgery. Ask questions. You and your surgeon will work together to help you to achieve the body image you desire.

WHAT GIVES THE BREAST ITS SHAPE?



The breast consists of milk ducts and glands, surrounded by fatty tissue that provides its shape and feel. Beneath the breast is the pectoralis major muscle (chest muscle) of the chest wall.

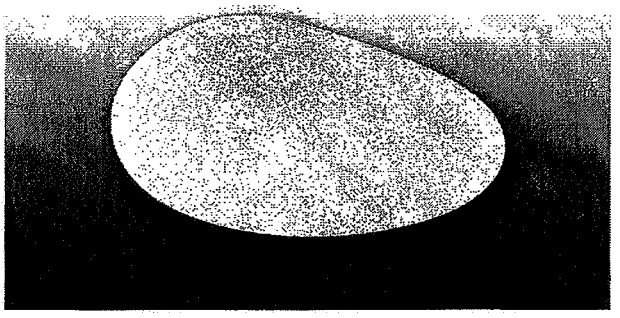
Women may choose breast reconstruction because they wish to restore breast shape following a mastectomy or injury to the breast or to correct a birth defect.

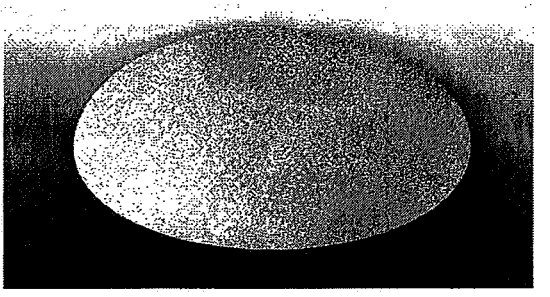
WHAT IS SILICONE?

Silicones are a family of compounds, made from silicon, a naturally occurring element. Silicones have been part of the consumer industry for over 50 years and because they can be manufactured in various ways, silicones appear in a wide variety of products most of us use everyday. Medical devices utilizing silicone include artificial joints, facial implants, catheters, tissue expanders and breast implants.

WHAT IS A SILICONE-FILLED BREAST IMPLANT?

A silicone-filled breast implant is a sac (implant shell) made of silicone elastomer (rubber) and filled with silicone gel. It is surgically implanted either under your breast tissue and above your chest muscle or below your chest muscle. Your plastic surgeon will discuss with you the best positioning for your implants.



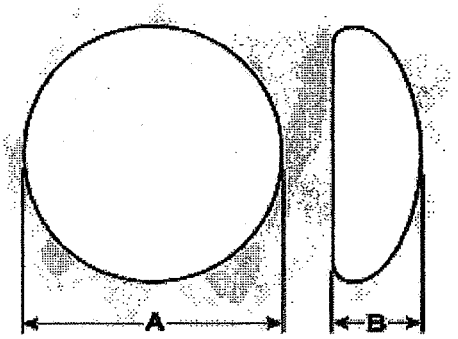


WHAT TYPES OF SILICONE-FILLED BREAST IMPLANTS ARE AVAILABLE FROM INAMED?

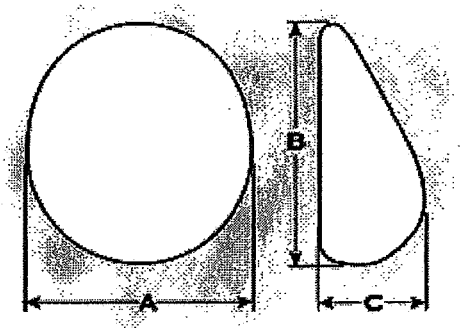
Breast implants come in a variety of shapes, surface textures, and sizes. INAMED manufactures several styles of round and one style of shaped silicone-filled breast implant (see below). They are available with smooth shell surfaces or textured shell surfaces. Your plastic surgeon will discuss with you the implant design that will best help you achieve your desired outcome.

Round Breast Implants:	
Style 10:	Smooth shell surface, moderate projection
Style 20:	Smooth shell surface, full projection
Style 40:	Smooth shell surface, standard projection
Style 45:	Smooth shell surface, full projection
Style 110:	BIOCELL® Textured shell surface, moderate projection
Style 120:	BIOCELL® Textured shell surface, full projection

Shaped Breast Implants:	
Style 153:	BIOCELL® Textured shell surface, double lumen, full height, full projection



A = Width; B = Projection
Round Breast Implant



A = Width; B = Height; C= Projection
Shaped Breast Implant

ARE SILICONE-FILLED BREAST IMPLANTS RIGHT FOR YOU?

In order to help you achieve your cosmetic goals safely, silicone-filled implants should not be used in women under the age of 18, in women with existing malignant or pre-malignant cancer of the breast who have not been successfully treated, in women with an active infection anywhere in the body, and in women who are currently pregnant or nursing.

In addition, silicone-filled breast implants have not been clinically testing in women with autoimmune diseases like lupus or scleroderma, in women with conditions that could interfere with wound healing and blood clotting, in women with a weakened immune system (such as women receiving immunosuppressive therapy), and in women with a reduced blood supply to the breast tissue. If you have any of these conditions or other serious health problems you should discuss with your surgeon whether breast reconstruction surgery is appropriate for you.

WHAT ARE THE BENEFITS OF BREAST RECONSTRUCTION SURGERY?

The benefits of breast reconstruction with silicone-filled breast implants are an improved cosmetic appearance and an improved body image and an increased self esteem.

WHAT YOU NEED TO KNOW BEFORE BREAST RECONSTRUCTION SURGERY

Before you agree to any surgical procedure, you need to fully understand the potential health risks that are associated with the surgery. If you are considering breast reconstruction, you also need to understand the potential health risks that may be associated with the long-term implantation of breast implants. These are described below.

THERE ARE RISKS ASSOCIATED WITH THE IMPLANT SURGERY.

All surgery carries some risk. The most commonly reported surgery-related risks for breast augmentation surgery are infection, bleeding, seroma, scarring, anesthesia, and pain.

Scarring

Most scars following breast augmentation are pale thin lines. However, they may become red, firm, and elevated. Some scars fade with time but scar revision may be desired.

Infection

Infection occurs very rarely following breast implant surgery. Most infections resulting from surgery appear within a few days to weeks after the operation, although infection is possible at any time after surgery. Infections with an implant present are harder to treat than infections in normal body tissues. Infections are typically treated with antibiotics, but if the infection does not respond to antibiotics, the implant may have to be removed. Another implant may be placed after the infection is resolved. In very rare instances, Toxic Shock Syndrome, a potentially life threatening condition, has been noted in women after breast implant surgery. Symptoms include sudden fever, vomiting, diarrhea, fainting, dizziness, and/or sunburn-like rash. You should see your surgeon immediately for diagnosis and treatment for this condition.

Hematoma

Bleeding (hematoma) occurs in 2-4% of breast implant procedures. It is usually seen soon after surgery, however, it can occur at any time after injury to the breast. While the body absorbs small hematomas, large ones will require the placement of surgical drains for proper healing. A small scar can result from surgical draining. Implant rupture can occur from surgical draining if damage to the implant occurs during the draining procedure.

Seroma

Seroma is a collection of the watery portion of the blood (in this case, around the implant or around the incision). While the body absorbs small seromas, large ones will require the placement of surgical drains for proper healing. A small scar can result from surgical draining. Implant rupture can occur from surgical draining if damage to the implant occurs during the draining procedure.

Anesthesia

As with all surgeries, there is a small risk that you will experience an adverse reaction to the anesthesia.

Pain

Pain of varying intensity and duration may occur and persist following breast implant surgery. In addition, improper size, placement, surgical technique, or capsular contracture may result in pain associated with nerve entrapment or interference with muscle motion. You should inform your surgeon if you experience severe pain.

YOU MAY NOT BE PLEASED WITH THE COSMETIC OUTCOME.

Dissatisfying results such as wrinkling, asymmetry (one breast is larger or smaller or a different shape than the other), implant displacement (shifting), incorrect size, unanticipated shape, implant palpability (ability to feel the implant under the skin), scar deformity, and/or hypertrophic (irregular, raised scar) scarring, may occur. Careful surgical planning and technique can minimize but not always prevent such results.

YOU MAY REQUIRE ADDITIONAL SURGERY AND SURGEON VISITS.

Breast implants are not considered lifetime devices. You may undergo implant removal with or without implant replacement during your lifetime.

MANY OF THE CHANGES TO YOUR BREAST FOLLOWING IMPLANTATION ARE IRREVERSIBLE.

If you later choose to have your implant(s) removed, you may experience unacceptable dimpling, puckering, or wrinkling of the skin or other cosmetic changes of the breast.

BREAST IMPLANTS MAY AFFECT YOUR ABILITY TO BREAST FEED.

Breast implant surgery may affect your ability to breast feed because the surgery may sever nerves that stimulate the body to release the hormones that trigger milk release. In addition, an incision around the nipple, which may be done to make the surgical scar less noticeable, also may sever ducts that drain milk from the mammary gland, such that even if the mother has an adequate milk supply, it may be difficult for the milk to drain into the nipple. Also, breast implants will not prevent a woman's breasts from sagging after pregnancy.

At this time it is not known if a small amount of silicone may diffuse (pass through) from the silicone-filled breast implant and may find its way into breast milk. If this occurs, it is not known what effect it may have on the nursing infant. Although there are no current methods for detecting silicone levels in breast milk, a study measuring silicon (one component in silicone) levels did not indicate higher levels in breast milk from women with silicone-filled breast implants when compared to women without implants.

BREAST IMPLANTS MAKE ROUTINE SCREENING MAMMOGRAPHY MORE DIFFICULT.

The presence of breast implants may interfere with finding breast cancer during mammography and also may make it difficult to perform mammography. Therefore, it is essential that you tell your mammography technologist that you have an implant before the procedure. The technologist can use special techniques to minimize the possibility of rupture and to get the best possible views of the breast tissue. You may wish to undergo a preoperative mammogram and another one 6 months to one year after implantation to establish a baseline.

Because the breast is squeezed during mammography, it is possible for an implant to rupture during the procedure. More x-ray views are necessary with these special techniques; therefore, women with breast implants will receive more radiation. However, the benefit of the mammogram in finding cancer outweighs the risk of the additional x-rays.

In addition to routine mammograms, women should perform a breast self-examination monthly on the implanted breast. In order to do this effectively, you should ask your surgeon to help you distinguish the implant from your breast tissue. Any new lumps or an abnormal finding on the mammogram should be evaluated with a biopsy. If a biopsy is performed, care must be taken to avoid puncturing the implant.

YOUR HEALTH INSURANCE PREMIUMS MAY INCREASE, COVERAGE MAY BE DROPPED, AND/OR FUTURE COVERAGE MAY BE DENIED.

Treatment of complications may not be covered as well. You should check with your insurance company regarding these coverage issues.

THE LONG-TERM SAFETY AND EFFECTIVENESS OF BREAST IMPLANTS HAVE NOT BEEN STUDIED.

INAMED is monitoring the long-term (10-year) chance of implant rupture, reoperation, implant removal, and capsular contracture (hardening of the tissues around the implant). INAMED is also conducting mechanical testing to assess the long-term likelihood of implant rupture. As new information becomes available, INAMED will issue an updated version of this brochure.

YOU HAVE OTHER OPTIONS.

There are alternatives to breast reconstruction with a silicone-filled breast implant. You may choose to have no treatment at all and accept your breast as they are. You may choose to wear an external prosthesis. Breast forms are available in a variety of shapes, sizes, and materials such as foam, cotton, and silicone. Custom prostheses are also available to match the size and shape of your breast. You may choose to have saline-filled implants implanted.

Breast reconstruction can be also be accomplished using your own tissues (a tissue flap) or a combination of the tissues and a prosthesis. The breast can be reconstructed by surgically moving a section of skin, fat and muscle from one area of your body to another. The section of tissue may be taken from such areas as your abdomen, upper back, upper hip, or buttocks. The tissue flap may be left attached to the blood supply and moved to the breast area through a tunnel under the skin (a pedicled flap) or it may be removed completely and reattached to the breast area by microsurgical techniques (a free flap). Operating time is generally longer with free flaps, because of the microsurgical requirements. Flap surgery requires a hospital stay of several days and generally a longer recovery time than implant reconstruction. Flap surgery also creates scars at the site where the flap was taken and on the reconstructed breast. However, flap surgery has the advantage of being able to replace tissue in the chest area. This may be useful when the chest tissues have been damaged and are not suitable for tissue expansion. Another advantage of flap procedures over implantation is that alteration of the unaffected breast is generally not needed to improve symmetry. The most common types of tissue flaps are the TRAM (transverse rectus abdominus musculocutaneous flap) (which uses tissue from the abdomen) and the latissimus dorsi flap (which uses tissue from the upper back). Flap surgery, particularly the TRAM flap, is a major operation, and more extensive than your mastectomy operation. It requires good general health and strong emotional motivation. If you are very overweight, smoke cigarettes, have had previous surgery at the flap site, or have any circulatory problems, you may not be a good candidate for a tissue flap procedure. Also, if you are very thin, you may

not have enough tissue in your abdomen or back to create a breast mound with this method.

SOME LOCAL COMPLICATIONS CAN OCCUR IN IMPLANTED BREASTS.

Local complications are sometimes observed in breast of women with silicone-filled implants. These include capsular contracture, rupture, calcification, implant extrusion, wound healing problems or tissue necrosis, visible skin wrinkling and rippling, changes in nipple and skin sensation, pain, malposition, asymmetry, breast tissue atrophy, and re-operation.

Capsular Contracture

The scar tissue or capsule that normally forms around the implant may tighten and squeeze the implant and is called capsular contracture. Capsular contracture may be more common following infection, hematoma, and seroma. It is also more common with subglandular placement (behind the mammary gland and on top of the chest muscle). Symptoms range from mild firmness and mild discomfort to severe pain, distorted shape, palpability of the implant, and/or movement of the implant.

Capsular contracture may occur on one side, both sides, or not at all. In severe cases, the disfigurement or discomfort resulting from capsular contracture may require surgery to remove the scar tissue around the implant and/or implant replacement. In some cases, the contracture may not be correctable and implant removal of the implant and capsule tissue may be necessary. Closed capsulotomy is not recommended due to concerns about implant rupture and localized bleeding. The occurrence of capsular contracture is not predictable, however, the chance of it happening increases with time. Capsular contracture may happen again after these additional surgeries.

Rupture

All implants, including breast implants, can fail over time and need to be removed or replaced. They are not to be considered life-time devices. Breast implants can rupture when the shell develops a hole or a tear. Some implants rupture in the first few months after being implanted and some rupture after several years. Rupture may be caused by damage to the implant by surgical instruments or other trauma to the implant during surgery, capsular contracture, closed capsulotomy, stresses such as trauma or intense physical manipulation after surgery, excessive compression during mammographic imaging and unknown/unexplained reasons.

Sometimes when an implant ruptures, the silicone gel filler is released from the implant shell. If that happens, the silicone gel is typically contained within the scar capsule that has formed around the implant. Rarely, the silicone gel filler may move beyond the fibrous capsule and into the breast tissue or away from the breast, particularly if the scar capsule is ruptured.

If an implant ruptures, removal or replacement of the implant may be necessary. Along with the rupture, patients may experience local complications, such as hard knots in the breast, uneven appearance of the breasts, pain or tenderness, tingling, swelling, numbness, burning, or changes in breast sensation. These complications may also be experienced by patients with non-ruptured implants. There is no evidence that silicone gel that moves beyond the breast capsule causes any symptoms or disease elsewhere in the body. However, most surgeons in INAMED's clinical studies have chosen to remove implants suspected of rupture. The decision to remove a ruptured implant with the presence of gel within or outside of the scar capsule should be undertaken following review of all available clinical information and after careful consideration between you and your surgeon.

A woman may not always notice if her implant has ruptured. Although there may be a change in the shape or size of the breast, as well as some physical symptoms, in some cases, there may be no detectable evidence of rupture. This is referred to as silent rupture. As a result, women with breast implants should periodically have their breast implants evaluated to determine if the implants have ruptured. While there are various diagnostic methods available to evaluate for possible implant rupture including physical examination, mammogram, and ultrasound, the U.S. Food and Drug Administration believes the best method for detection of rupture is Magnetic Resonance Imaging (MRI). MRI screening should be performed every 1-2 years or at a frequency recommended by your plastic surgeon. INAMED's clinical study results and other published reports have found that in some cases MRI may falsely show a breast implant rupture when there is none. The decision to remove a suspected ruptured implant should be undertaken following discussion between you and your surgeon.

Gel Bleed

There is no evidence from the medical literature or from Inamed's own testing suggesting that gel bleed (gel components passing through the shell) may be associated with local complications in breast implant patients. In addition, clinical study patients in Inamed's Core clinical study for silicone-filled breast implants were at no higher risk of local complications when compared to the risk of local complications reported in Inamed's 1995 saline-filled breast implant clinical study.

Calcium Deposits

Deposits of calcium can be seen on mammograms and although they are benign, they can be mistaken for possible cancer, resulting in additional surgery for biopsy and/or removal of the implant to distinguish the calcium deposits from cancer.

Implant Extrusion

If the skin or breast tissue covering the implant is very thin and/or there is a problem with healing, the implant may break through the skin and become exposed. This will require removal of the implant.

Wound Healing Problems or Tissue Necrosis

Some patients experience delayed healing of the incision site or they may not heal well. This can result in an unattractive scar and if the implant is exposed, further surgery will be required. Tissue breakdown or necrosis (the formation of dead tissue around the implant) will delay wound healing, may cause wound infection, and may require surgical correction and/or implant removal. Permanent scar deformity may occur following necrosis. Factors associated with increased necrosis include infection, use of steroids in the surgical pocket, smoking, chemotherapy/radiation, and excessive heat or cold therapy.

Visible Skin Wrinkling and Rippling

Visible rippling can result when an implant pulls on the overlying tissues or when the natural folds in the implant are visible through the skin. Removal and replacement of the implant may correct this problem.

Change in Nipple and Skin Sensation

Some change in nipple sensation is not unusual right after surgery and after several months, most patients have normal sensation. Only rarely does permanent loss of nipple and skin sensation or hypersensitivity occur. The range of changes varies from intense sensitivity to no feeling in the nipple or breast following surgery. Changes in feeling can be temporary or permanent and may affect your sexual response or your ability to nurse a baby.

Pain

Pain of varying intensity and duration may occur and persist following breast implant surgery. In addition, improper size, placement, surgical technique, or capsular contracture may result in pain associated with nerve entrapment or interference with muscle motion. You should tell your surgeon about any severe pain you may experience.

Malposition

Breast malposition may result from shifting after initial placement, excessive sagging or stretching of the lower breast, or capsular contracture. Removal and replacement of the implant may correct this problem.

Asymmetry

Asymmetry (differences in size or shape between breasts) can result from some of the above-mentioned complications. Most women's breasts have at least some asymmetry, even without implants. Removal and replacement of the implant may correct this problem.

Breast Tissue Atrophy

Pressure from breast implants may cause the surrounding tissue to thin or shrink and this may result in the implant becoming more visible or palpable. This can occur while implants are still in place or following implant removal without replacement.

Re-operation

Implanted devices do not last forever, and like many other implanted devices may need to be replaced or removed after a period of time. The rates of re-operation reported in the literature for noncosmetic reasons range from 10 to 30%. Patients should expect to have additional surgery at some point to replace or remove the implant. Also, problems such as rupture, capsular contracture, infection, shifting, and calcium deposits can require removal of the implants. Many women decide to have the implants replaced, but some women do not. If you choose not to, you may have cosmetically unacceptable dimpling and/or puckering of the breast following removal of the implant.

THERE IS A CONCERN THAT BREAST IMPLANTS INCREASE THE RISK OF CERTAIN DISEASES OR EVENTS.

There has been discussion in the scientific and regulatory communities regarding the potential for silicone-filled breast implants to be associated with certain systemic diseases or concerns. The strength of these associations between breast implants and connective tissue disease, cancer, nervous system effects, effects on children, and suicide is discussed below.

Connective Tissue Disease

Concern over the association of breast implants to the development of autoimmune or connective tissue diseases, such as lupus, scleroderma, or rheumatoid arthritis, was raised because of cases reported in the literature with small numbers of women with implants. Several large epidemiological studies of women with and without implants indicate that these diseases are no more common in women with implants than those in women without implants.

Some patients in INAMED's Core Clinical Study showed an increase over time in some CTD signs and symptoms and those CTD signs and symptoms specific to fibromyalgia, such as fatigue, swelling, weakness, aches, back and neck pain. However, patients with INAMED's saline-filled implants showed similar increases in these signs and symptoms. This indicates that the increased signs and symptoms are most likely not caused by the silicone-filled breast implants and may be attributed to other factors such as aging.

Cancer and Benign Breast Disease

The overwhelming majority of epidemiological studies indicate that cancer and benign breast disease are no more common in women with implants than those without implants, thus offering compelling scientific evidence of a lack of association between breast implants and cancers.

Nervous System Effects

Most investigators report no causal relationship between the presence of breast implants and neurological effects including Meniere's disease, hearing loss, and neurological disease, including multiple sclerosis and Guillain-Barre syndrome.

Effects on Children of Women with Breast Implants

The concern that children born to mothers with silicone breast implants are at risk of developing health problems stems from reports of children born to or breastfed by such women who developed swallowing difficulties, irritability, nonspecific skin rashes, fatigue, and other symptoms. However, epidemiological investigations have not found any increased risk of adverse health outcomes, including occurrence of esophageal disorders, connective tissue disease, and congenital malformations in children born to women with breast implants.

Suicide

Some investigators have raised concerns that the risk of suicide is increased in patients with silicone-filled breast implants. However, their studies do not consider other factors that are likely to affect a woman's predisposition for suicidal tendencies and that are widely acknowledged to be more common among women who seek breast implants, such as cigarette smoking, alcohol consumption, weight, parity, low self-esteem, depression, or other psychiatric/emotional disorders.

WHAT EVIDENCE IS THERE THAT INAMED SILICONE-FILLED IMPLANTS ARE SAFE AND EFFECTIVE?

Although you will experience your own risks (complications) and benefits following breast implant surgery, this section describes the specific complications and benefits of INAMED silicone-filled breast implants. INAMED's studies of women seeking reconstruction with silicone-filled breast implants indicate, for example, that about 1 in 2 reconstruction patients (47%) can expect to experience additional breast surgery at some point through 3 years after implant surgery. The information below provides more details about the complications and benefits you may experience.

LABORATORY AND ANIMAL TESTING

Laboratory and animal testing of INAMED's silicone-filled breast implants revealed that the materials of which the implants are manufactured are safe, the silicone elastomer shell is durable, and there is a low potential for the implant to leak or rupture. Testing conducted by INAMED also revealed that only minimal amounts of the silicone gel filler bleed across an intact silicone elastomer shell over time and that the constituents (components) of this gel do not pose a health concern.

STUDIES IN WOMEN

INAMED conducted clinical studies testing of its silicone-filled breast implants to determine the short-term and most common complications as well as the benefits of its implants. The Core Clinical Study was designed as a 10-year study to assess all complications as well as patient satisfaction, body image, body esteem, and self concept. Patients were followed annually, and data through 3 years after implantation are currently available. The Core Study enrolled 221 reconstruction patients. Of those reconstruction patients available to be seen at the 3-year follow-up visit, 94% were seen.

Complications Reported in the Core Study

The 3-year complication rates are shown from the most common to the least common in the table below. The rates reflect the number of reconstruction patients out of 100 who experienced the listed complication at least once within the first 3 years after implantation. Some complications occurred more than once for some patients. The two most common complications experienced within the first 3 years of implantation were capsular contracture (15% or 15 patients out of 100) and asymmetry (13% or 13 patients out of 100). Some complications required patients to undergo an additional breast surgery in order to address the complication. The following table shows all complications (i.e., those that lead to additional surgery and those that did not.)

Complication*	3-Year Complication Rate
Capsular Contracture	15%
Asymmetry	13%
Implant Malposition	8%
Rupture	7%
Breast Pain	6%
Scarring, Redness, Seroma/Fluid Accumulation, Tissue or Skin Necrosis, Wrinkling, Delayed Wound Healing, Swelling	2-5%
Hematoma, Skin Rash, Implant Extrusion*, Infection, Bruising	1%
Nipple Hypersensitivity/Paresthesia, Complications, Pneumothorax*, Ptosis, Implant Palpability/Visibility	<1%
Not Occurring: Capsule Calcification, Irritation, Lymphadenopathy, Lymphedema, Loss of Skin Sensation, Skin Hypersensitivity/Paresthesia, Loss of Nipple Sensation, Other Nipple Complications, Other Complications	0%

*All complications were assessed with severity ratings. Most rates shown in the table include only complications rated moderate, severe, or very severe (excludes mild and very mild ratings). The only complication rates that include all severity ratings are rupture, pneumothorax, and implant extrusion.

Additional Surgeries

Some of the complications reported in the above table led to an additional surgery and some additional surgeries involved removal of the implant. A patient's risk of an additional surgery or implant removal is 47% risk of additional surgery through 3 years and 22% risk of implant removal through 3 years.

Through 3 years, 102 reconstruction patients had at least one additional surgery, and some patients required multiple surgeries. A total of 144 additional surgeries were performed through 4 years. Although some complications led to an additional surgery, many complications do not require additional surgery and many additional surgeries are performed without removal of the implant. 46 of the 101 patients had an implant removed. For example, a patient's risk of capsular contracture is 15%; however, a patient's risk of a capsular contracture that requires additional surgery is less, at 6%, and a patient's risk of having the implant removed to treat the capsular contracture is even lower at 2%. The following table describes a patient's risk of having an additional surgery or implant removal for the complications listed in the previous table.

(Because rupture is addressed in the next section, it is not included in the following table.)

Complication	% Risk of Complication Leading to Additional Surgery	% Risk of Complication Leading to Removal/Replacement
Asymmetry	12.1%	9.2%
Breast Pain	<1%	<1%
Capsular Contracture	6%	2%
Hematoma	1%	<1%
Scarring	14.7%	0.5%
Implant Malposition	15.8%	6.8%
Implant Palpability	0%	0%
Loss of Skin Sensation	0%	0%
Nipple Complication	0%	0%
Ptosis	2.9%	1.0%
Skin Rash	0%	0%
Swelling	0%	0%
Patient Request for Style/Size Change	10.1%	9.6%
Other	5.5%	4.0%
Breast Tissue Contour Deformity	3.8%	1.1%
Need for Biopsy	3.1%	0.5%
Delayed Wound Healing	2.3%	0%
Breast Cancer	1.0%	1.0%
Wrinkling/Rippling	1.0%	1.0%
Extrusion	1.0%	0.5%
Injury (surgery related or traumatic)	0.5%	0.5%
Necrosis	0.5%	0.0%

Rupture

Through 3 years, both silent and symptomatic (i.e., non-silent) ruptures have been detected in the reconstruction patients. The 3-year rates of these events are described as 11% risk of any rupture, 10% risk of silent rupture, and < 1% risk of symptomatic rupture. These risks are calculated by-implant rather than by-patient because the complication is implant-specific.

Some silent ruptures were discovered using MRI. A portion of the study participants underwent routine screening with MRI. Of the implants that were diagnosed as ruptured and later explanted, the Core Study showed 36-37% of the MRI-diagnosed implants to be intact.

Other Events

Through 3 years, events other than the complications described in the previous tables above were collected in the Core Clinical Study. Some of these events, such as breast cancer and connective tissue disease, can occur in non-implanted patients. Therefore, without a comparison group of women with similar characteristics (such as age, race, etc.) and without breast implants, no conclusions can be made about the relationship between breast implants and some of these other events. These events are described in the following table.

Event	Reconstruction 3-Year Rate
Biopsy Procedure	3%
Malignant Breast Cancer	0%
Benign Breast Cancer	9%
Unknown Breast Cancer (i.e., not yet diagnosed)	1%
CTD – Systemic Sclerosis/Scleroderma	<1%
Implant Removal due to Patient Request for Size/Style Change	10%
Implant Removal due to Patient's Request	0%

Benefits of Implantation

The benefits of silicone-filled breast implants were assessed by a variety of outcomes, including patient satisfaction, body image, body esteem, and self concept. These outcomes were assessed for patients with both original and replacement silicone devices before implantation and at every follow-up visit, except for quality-of-life concepts which was measured at baseline and at follow-up visit 1, 2, and 4 years.

185 of the original 221 patients were included in an analysis of satisfaction at 3 years. Of these 185 patients, 92% indicated being satisfied with their breast implants at 4 years.

The Quality-of Life patient surveys showed that reconstruction patients scored higher (better) than the general U.S. female population on questions measuring general health-related quality of life. After 2 years, the patients responses to the general health related quality of life did not change, this indicated they remained higher than the U.S. female population. Patient responses to questions regarding overall self-concept and overall self esteem (did not increase or decrease self concept/esteem) over the 2 years after receiving implants. Furthermore, patient

responses to questions regarding overall self esteem related specifically to one's body remained constant over the 2 years after receiving implants.

SOME PRACTICAL ASPECTS OF BREAST RECONSTRUCTION SURGERY

When considering breast augmentation surgery, it is important for you to have confidence in your plastic surgeon and the surgical approach and device design he or she has chosen for you. The following information provides you with some information relating to the more practical aspects of breast implantation surgery.

CHOOSING A PLASTIC SURGEON

When choosing a surgeon who is experienced with breast implantation, you should know the answers to the following questions:

1. How many breast reconstruction implantation procedures does he/she perform per year?
2. How many years has he/she performed breast implantation procedures?
3. Is he/she board certified, and if so, with which board?
4. In which states is he/she licensed to practice surgery? Note that some states provide information on disciplinary action and malpractice claims/settlements to prospective patients either by request or on the worldwide web.
5. What is the most common complication he/she encounters with breast implantation?
6. What is his/her reoperation rate with breast implantation and what is the most common type of reoperation he/she performs?

QUESTIONS TO ASK THE PLASTIC SURGEON ABOUT BREAST RECONSTRUCTION

The following list of questions may help to remind you of topics to discuss with your surgeon. You may have additional questions as well.

1. What are all my options for breast reconstruction?
2. What are the risks and complications of each type of breast reconstruction surgery and how common are they?
3. What if my cancer recurs or occurs in the other breast?
4. Will reconstruction interfere with my cancer treatment?
5. How many steps are there in each procedure and what are they?
6. How long will it take to complete my reconstruction?

7. How much experience do you have with each procedure?
8. Do you have before and after photos I can look at for each procedure and what results are reasonable for me?
9. What will my scars look like?
10. What kind of changes in my implanted breast can I expect over time?
11. What kind of changes in my implanted breast can I expect with pregnancy?
12. What are my options if I am dissatisfied with the cosmetic outcome of my implanted breast?
13. Can I talk with other patients about their experiences?
14. What is the estimated total cost of each procedure?
15. How much will my health insurance carrier cover, especially any complication that may require surgery?
16. How much pain or discomfort will I feel, and for how long?
17. How long will I be in the hospital?
18. Will I need blood transfusions, and can I donate my own blood?
19. When will I be able to resume my normal activity (or sexual activity, or athletic activity)?

WHAT SIZE AND DESIGN OF IMPLANT TO CHOOSE

Familiarize yourself with the following options in breast implant surgery and be prepared to discuss with your surgeon the following issues:

Implant Shape and Size

Depending on the desired shape you wish to achieve, you and your surgeon may choose a round or contoured implant shape. Generally, the larger you want your cup size, the larger the breast implant the surgeon will consider (measured in cubic centimeters, or cc's). Contoured implants that are placed submuscularly (under your chest muscle) may assume a round shape after implantation.

Your surgeon will also evaluate your existing tissue to determine if you have enough to cover the breast implant. If you desire a breast implant size too large for your tissue, the surgeon may warn you that breast implant edges may be apparent or visible post-operatively. You may even risk surgical complications. Also, excessively large breast implants may speed up the effects of gravity and result in earlier droop or sag.

Implant Surface Texturing

Textured surface implants were designed to reduce the chance of capsular contracture. Some information in the literature with small numbers of patients

suggests that surface texturing reduces the chance of severe capsular contracture, but clinical information from studies of a large number of women with INAMED implants shows no difference in the likelihood of developing capsular contracture with textured implants compared to smooth-surfaced implants.

Palpability

The following may cause implants to be more palpable (more easily felt): textured implants, larger implants, subglandular placement, and the amount of skin/tissue available to cover the implant.

WHAT TYPE OF SURGICAL APPROACH IS BEST FOR YOU?

Women with small or medium sized breasts are the best candidates for breast reconstruction. Reconstruction patients commonly undergo additional surgeries to improve breast symmetry and appearance. For example, because the nipple and areola are usually removed with the breast tissue in mastectomy, the nipple is usually reconstructed by using a skin graft from another area of the body or the opposite breast, in addition to tattooing the area. Nipple reconstruction is usually done as a separate outpatient procedure after the initial reconstruction surgery is complete.

Your surgeon will decide whether your health and medical condition makes you an appropriate candidate for breast implant reconstruction. Women with larger breasts may require reconstruction with a combination of a tissue flap and an implant. Your surgeon may recommend breast implantation of the opposite, uninvolved breast in order to make your breasts more alike (maximize symmetry) or he/she may suggest breast reduction (reduction mammoplasty) or a breast lift (mastopexy) to improve symmetry. Mastopexy involves removing a strip of skin from under the breast or around the nipple and using it to lift and tighten the skin over the breast. Reduction mammoplasty involves removal of breast tissue and skin. If it is important to you not to alter the unaffected breast, you should discuss this with your plastic surgeon, as it may affect the breast reconstruction methods considered for your case.

Reconstruction Incision Sites

Most implants in breast reconstruction use the mastectomy scar either immediately (during the mastectomy procedure) or after tissue expansion.

Surgical Setting and Anesthesia

Reconstruction surgery is usually performed on an inpatient basis in an operating room. General anesthesia is most often used.

The Timing of Your Breast Implant Reconstruction

The following description applies to reconstruction following mastectomy, but similar considerations apply to reconstruction following breast trauma or for reconstruction for congenital defects. The breast reconstruction process may begin at the time of your mastectomy (immediate reconstruction) or weeks to years afterwards (delayed reconstruction). Immediate reconstruction may involve placement of a breast implant but typically involves placement of a tissue expander, which will eventually be replaced with a breast implant. It is important to know that any type of surgical breast reconstruction may take several steps to complete.

Two potential advantages to immediate reconstruction are that your breast reconstruction starts at the time of your mastectomy and that there may be cost savings in combining the mastectomy procedure with the first stage of the reconstruction. However, there may be a higher risk of complications such as deflation with immediate reconstruction, and your initial operative time and recuperative time may be longer.

A potential advantage to delayed reconstruction is that you can delay your reconstruction decision and surgery until other treatments, such as radiation therapy and chemotherapy, are completed. Delayed reconstruction may be advisable if your surgeon anticipates healing problems with your mastectomy or if you just need more time to consider your options.

There are medical, financial, and emotional considerations to choosing immediate versus delayed reconstruction. You should discuss with your surgeon, plastic surgeon, and oncologist, the advantages and disadvantages of immediate reconstruction with a breast implant, expander-assisted immediate reconstruction, and delayed reconstruction.

THE BREAST IMPLANT RECONSTRUCTION PROCEDURE

The procedure for reconstruction of a breast utilizing a silicone-filled breast implant differs depending on whether the reconstruction is immediate or delayed and whether it involves a tissue expander.

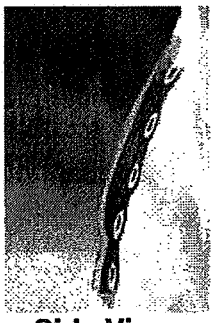
Immediate or Delayed Breast Implant Reconstruction

Immediate breast reconstruction using only a breast implant may be done at the time of your mastectomy or sometime after. After the general surgeon removes your breast tissue, the plastic surgeon will then implant a breast implant that completes the reconstruction. In reconstruction following mastectomy, a breast implant is most often placed submuscularly.

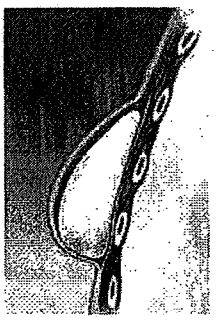
Expander-Assisted (Immediate or Delayed) Breast Implant Reconstruction

Breast reconstruction usually occurs as a multistage procedure, starting with the placement of a breast tissue expander, which is replaced several months later with a

breast implant. The tissue expander placement may be done immediately, at the time of your mastectomy, or be delayed until months or years later.



Side View, Breast Tissue Removed



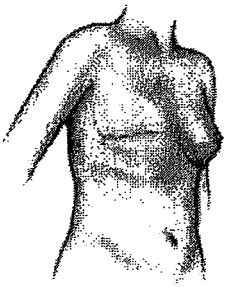
Side View, Expander Inserted and Filled

Stage 1: Tissue Expansion
During a mastectomy, the general surgeon removes skin as well as breast tissue, leaving the chest tissues flat and tight. To create a breast shaped space for the breast implant, a tissue expander is placed under the remaining chest tissues.

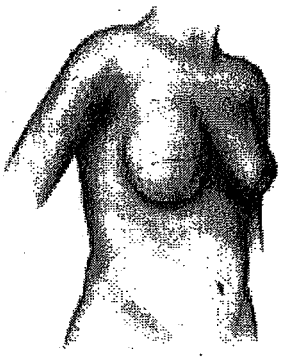
The tissue expander is a balloon-like device made from elastic silicone rubber. It is inserted unfilled, and over time, sterile saline fluid is added by inserting a small needle through the skin to the filling port of the device. As the tissue expander fills, the tissues over the expander begin to stretch, similar to the gradual expansion of a woman's abdomen during pregnancy. The tissue expander creates a new breast-shaped pocket for a breast implant.
Tissue expander placement usually occurs under general anesthesia in an operating room. Operative time is generally 1 to 2 hours. The procedure may require a brief hospital stay, or be done on an outpatient basis. Typically, you can resume normal daily activity after 2 to 3 weeks.

Because the chest skin is usually numb from the mastectomy surgery, it is possible that you may not experience pain from the placement of the tissue expander. However, you may experience feelings of pressure, tightness or discomfort after each filling of the expander, which subsides as the tissue expands but may last for a week or more. Tissue expansion typically lasts four to six months.

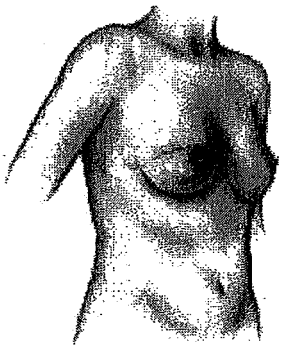
Stage 2: Placing the Breast Implant
After the tissue expander is removed, the breast implant is placed in the pocket. In reconstruction, following mastectomy, a breast implant is most often placed submuscularly. The surgery to replace the tissue expander with a breast implant (implant exchange) is usually done under general anesthesia in an operating room. It may require a brief hospital stay or be done on an outpatient basis.



Post Mastectomy



Stage 1: Tissue Expander Placed and Expansion Underway



Stage 2: Breast Implant and Nipple/Areola Reconstruction

BREAST RECONSTRUCTION WITHOUT IMPLANTS: TISSUE FLAP PROCEDURES

The breast can be reconstructed by surgically moving a section of skin, fat and muscle from one area of your body to another. The section of tissue may be taken from such areas as your abdomen, upper back, upper hip, or buttocks.

The tissue flap may be left attached to the blood supply and moved to the breast area through a tunnel under the skin (a pedicled flap), or it may be removed completely and reattached to the breast area by microsurgical techniques (a free flap). Operating time is generally longer with free flaps, because of the microsurgical requirements.

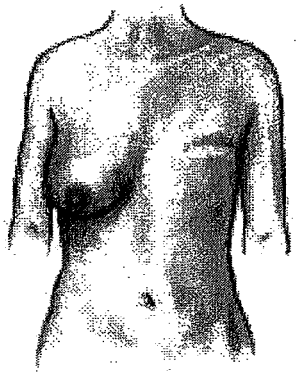
Flap surgery requires a hospital stay of several days and generally a longer recovery time than implant reconstruction. Flap surgery also creates scars at the site where the flap was taken and on the reconstructed breast. However, flap surgery has the advantage of being able to replace tissue in the chest area. This may be useful when the chest tissues have been damaged and are not suitable for tissue expansion. Another advantage of flap procedures over implantation is that alteration of the unaffected breast is generally not needed to improve symmetry.

The most common types of tissue flaps are the TRAM (transverse rectus abdominus musculocutaneous flap) (which uses tissue from the abdomen) and the Latissimus dorsi flap (which uses tissue from the upper back).

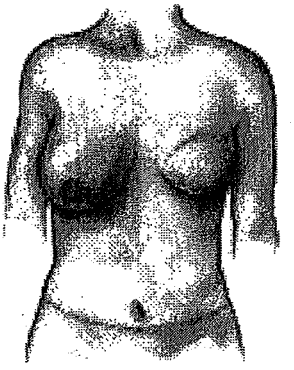
It is important for you to be aware that flap surgery, particularly the TRAM flap, is a major operation, and more extensive than your mastectomy operation. It requires good general health and strong emotional motivation. If you are very overweight, smoke cigarettes, have had previous surgery at the flap site, or have any circulatory problems, you may not be a good candidate for a tissue flap procedure. Also, if you are very thin, you may not have enough tissue in your abdomen or back to create a breast mound with this method.

THE TRAM FLAP (PEDICLE OR FREE)

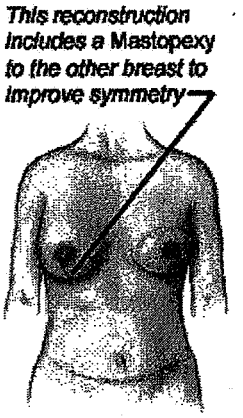
During a TRAM flap procedure, the surgeon removes a section of tissue from your abdomen and moves it to your chest to reconstruct the breast. The TRAM flap is sometimes referred to as a "tummy tuck" reconstruction, because it may leave the stomach area flatter.



Post Mastectomy



TRAM Flap



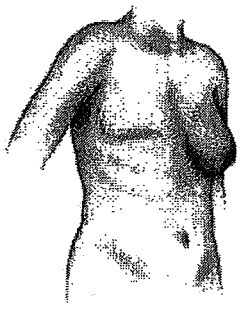
Final Result with Nipple/Areola Reconstruction

A pedicle TRAM flap procedure typically takes three to six hours of surgery under general anesthesia; a free TRAM flap procedure generally takes longer. The TRAM procedure may require a blood transfusion. Typically, the hospital stay is two to five days. You can resume normal daily activity after six to eight weeks. Some women, however, report that it takes up to one year to resume a normal lifestyle. You may have temporary or permanent muscle weakness in the abdominal area. If you are considering pregnancy after your reconstruction, you should discuss this with your surgeon. You will have a large scar on your abdomen and may also have additional scars on your reconstructed breast.

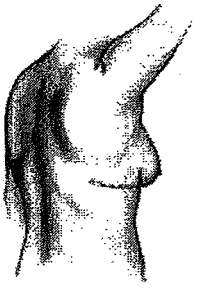
THE LATISSIMUS DORSI FLAP WITH OR WITHOUT BREAST IMPLANTS

During a Latissimus Dorsi flap procedure, the surgeon moves a section of tissue from your back to your chest to reconstruct the breast. Because the Latissimus Dorsi flap is usually thinner and smaller than the TRAM flap, this procedure may be more appropriate for reconstructing a smaller breast.

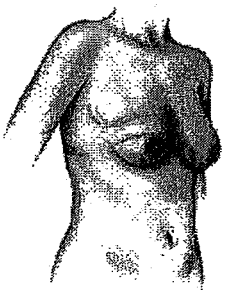
The Latissimus Dorsi flap procedure typically takes two to four hours of surgery under general anesthesia. Typically, the hospital stay is two to three days. You can resume daily activity after two to three weeks. You may have some temporary or permanent muscle weakness and difficulty with movement in your back and shoulder. You will have a scar on your back, which can usually be hidden in the bra line. You may also have additional scars on your reconstructed breast.



Post Mastectomy



View Showing Back Scar



Latissimus Dorsi Flap and Nipple/Areola Reconstruction

REGISTERING YOUR BREAST IMPLANT

INAMED Corporation maintains a device registry to identify patients who have INAMED's silicone-filled breast implants. The registry is designed to collect demographic and contact information for patients who are implanted with INAMED's silicone-filled breast implants. In addition, registration of your device can assist INAMED in handling problems you experience with your implants and in processing ConfidencePlus™ claims.

With patient consent, information collected in the device registry may be provided to assist with national breast implant surveys conducted by, for example, the National Institutes of Health (NIH).

INAMED strongly recommends that all patients receiving silicone-filled breast implants be registered in this database.

Successful device registration begins with the **Medical Device Registration Form** that is supplied with every breast implant. After surgery your doctor should provide you with the Medical Device Registration Form. The top portion of the form will have been completed with device specific information. The rest of the form should be completed by you and returned to INAMED Corporation in the postage paid envelope provided.

Device Identification Card

You will also be given a device identification card with the style and serial number of your breast implant(s). This card is for your permanent record and should be kept in a safe place. In the event you have a concern or problem with your implant you can use this card to describe the implant to your health care provider or to INAMED.

WHAT YOU NEED TO KNOW AFTER THE SURGERY

Once your surgery is complete, there are a few things you can do to minimize the likelihood that you will experience serious complications.

TAKING CARE OF YOUR IMPLANTS AND YOURSELF

You will probably feel somewhat tired and sore for several days following the operation, and your breast may remain swollen and sensitive to physical contact for a month or longer. Depending on the type of surgery you have (i.e., immediate or delayed), the post-operative recovery period will vary.

Post-operative care may involve the use of a post-operative bra, compression bandage, or jogging bra for extra support and positioning while you heal. At your surgeon's recommendation, you will most likely be able to return to work within a few days, although you should avoid any strenuous activities that could raise your pulse and blood pressure for at least a couple of weeks. Your surgeon may also recommend breast massage exercises. If you experience fever, or noticeable swelling and/or redness in your implanted breast(s), you should contact your surgeon immediately.

Once you are healed, you should be routinely monitored for implant ruptures with physical examination by your physician and MRI. Your physician may recommend removal of confirmed or suspected ruptured devices.

IF YOU EXPERIENCE A PROBLEM

You should report any problems that you notice with your implants immediately to your plastic surgeon. If you believe that you have experienced a serious problem(s) related to your breast implants, you should have your health professional report the problem(s) to FDA. You may also report any serious problem directly through the FDA's MedWatch voluntary reporting system. An adverse event is serious and should be reported when it results in an initial or prolonged hospitalization, disability, congenital anomaly, or medical or surgical intervention. This information reported to MedWatch is entered into databases to be used to follow safety trends (patterns) of a device and to determine whether further follow-up of any potential safety issues related to the device is needed.

To report, use MedWatch form 3500 which may be obtained through FDA's website at http://www.fda.gov/medwatch/index.html. You may also call 1.888.463.INFO.FDA (1.888.463.6332), from 10:00am-4:00pm Eastern Time, Monday through Friday to receive an additional FDA MedWatch Package. Keep a copy of the MedWatch form completed by your surgeon for your records.

IF YOU NEED TO REPLACE A FAILED IMPLANT

The ConfidencePlus™ Limited Warranties provide lifetime replacement and limited financial reimbursement in the event of loss of shell integrity resulting in implant deflation or rupture, subject to certain conditions as fully discussed in the

ConfidencePlus™ literature. For more information, please contact Product Support at 800.624.4261.

HOW TO RECEIVE MORE INFORMATION

If after reading this booklet, you have additional questions about breast implants or breast implant surgery, there are a number of resources available to you.

TOLL-FREE NUMBER

If you are a patient or a prospective patient and wish to speak to an INAMED Aesthetics product support specialist to inquire about breast implants or discuss any concerns, call toll free at 800.362.4426.

GENERAL RESOURCES ABOUT IMPLANTS

Upon request to INAMED or to your plastic surgeon, you will be provided with a copy of the Directions for Use (package insert). For more detailed information on the preclinical and clinical studies conducted by INAMED, you are referred to the Summary of Safety and Effectiveness Data for this product at http://www.fda.gov/cdrh/pdf/TBD.html.

You will also be given a device identification card with the style and serial number of your breast implant(s).

BREAST RECONSTRUCTION RESOURCES

The following list of resources may help you to find more information and support for your breast reconstruction decision.

National Cancer Institute
1-800-4-CANCER
www.cancernet.nci.nih.gov

American Cancer Society (Reach to Recovery)
1-800-ACS-2345
www.cancer.org

Y-ME National Organization for Breast Cancer Information and Support
1-800-221-2141
www.y-me.org

ADDITIONAL RESOURCES

INAMED Aesthetics
1-800-624-4261
www.inamedaesthetics.com

Institute of Medicine Report on the Safety of Silicone Implants
www.nap.edu/catalog/9618.html

Food and Drug Administration
1-888-INFO-FDA or 301-827-3990
www.fda.gov/cdrh/breastimplants/

FDA Breast Implant Consumer Handbook - 2004
http://www.fda.gov/cdrh/breastimplants/indexbip.html
http://www.fda.gov/cdrh/breastimplants/indexbip.PDF

GLOSSARY OF MEDICAL/TECHNICAL TERMS

Areola	The pigmented or darker colored area of skin surrounding the nipple of the breast.
Asymmetry	A lack of proportion of shape, size and position on opposite sides of the body.
Autoimmune Disease	A disease in which the body mounts an "attack" disease response to its own tissues or cell types. Normally, the body's immune mechanism is able to distinguish clearly between what is a normal substance and what is foreign. In autoimmune diseases, this system becomes defective and produces antibodies against normal parts of the body, causing tissue injury. Certain diseases such as rheumatoid arthritis and scleroderma are considered to be autoimmune diseases.
Axillary	Pertaining to the armpit area.
Bilateral	Pertaining to both the left and right breast.
Biopsy	Removal and examination of sample tissue for diagnosis.
Breast Augmentation	Enlargement of the breast by surgical implantation of a breast implant or patient's own tissue.
Breast Reconstruction	Surgical restoration of natural breast contour and mass following mastectomy, trauma or injury.
Breast Revision	Revision surgery is a plastic surgery procedure to correct or refine the outcome of a previous breast surgery. The revision may involve the replacement of a breast implant.
Capsular Contracture	Tightening of the tissue surrounding a breast implant which results in a firmer breast.
Capsulectomy	Surgical removal of the entire capsule surrounding a breast implant.
Capsulotomy	Closed Capsulotomy: Compression on the outside of the breast to break the capsule and relieve contracture. Open Capsulotomy: Surgically cutting or removing part of the capsule through an incision.
Carcinoma	Invasive malignant tumor.
Congenital Anomaly	Abnormality existing at birth.
Connective Tissue Disease (CTD)	A disease or group of diseases affecting connective tissue. The cause of these diseases are unknown. The diseases are grouped together on the basis of clinical signs, symptoms, and laboratory abnormalities.
Rupture	Refers to loss of saline from a saline-filled breast implant due to a tear or cut in the implant shell or possibly a valve leak.
Displacement	Shifting in the original position.
Epidemiological	Pertaining to the cause, distribution and control of disease in populations.
Extrusion	A breast implant or tissue expander being pressed out of the body.

Fibrous Tissue	Tissue resembling fibers.
Gel Bleed	Gel components passing through the shell.
Hematoma	A swelling or mass of blood (usually clotted) confined to an organ, tissue, or space and caused by a break in a blood vessel.
Immune Response	The reaction of the body to substances that are foreign or are interpreted as being foreign.
Inframammary	Below the breast.
Inframammary Fold	The crease at the base of the breast and the chest wall.
Inframammary Incision	A surgical incision at the inframammary fold.
In-Patient Surgery	Surgery performed in a hospital requiring an overnight stay
Latissimus Dorsi	Two triangular muscles running from the spinal column to the shoulder.
Mammaplasty	Plastic surgery of the breast.
Mammary	Pertaining to the breast.
Mammography	Use of radiography (X-rays) of the breast to detect breast cancer. Recommended as a screening technique for early detection of breast cancer.
Mastectomy	Surgical removal of the breast. Subcutaneous Mastectomy: Removal of breast tissue, preserving the skin and nipple. Partial Mastectomy: Removal of primary tumor and a wide margin of tissue, may include the overlying skin and the muscle fibrous tissue (fascia) underlying the tumor. Total (Simple) Mastectomy: Removal of breast tissue and the nipple; sometimes accompanied by armpit (axillary) node dissection. Modified Radical Mastectomy: Removal of breast tissue, nipple, and fascia of chest (pectoralis) muscle with axillary node dissection.
Mastopexy	Plastic surgery to move sagging (ptotic) breasts into a more elevated position.
Necrosis	Death of tissue. May be caused by insufficient blood supply, trauma, radiation, chemical agents or infectious disease.
Oncologist	A specialist in the branch of medicine dealing with the study and treatment of tumors.
Out-Patient Surgery	Surgery performed in a hospital or surgery center not requiring an overnight stay.
Palpate/Palpability	To feel with the hand.
Pectoralis	The major muscle of the chest.
Plastic Surgery	Surgery intended to improve, restore, repair, or reconstruct portions of the body following trauma, injury or illness.

Prosthesis	An artificial device used to replace or represent a body part.
Ptosis	Sagging of the breast usually due to normal aging, pregnancy or weight loss.
Rectus Abdominus	Major abdominal (stomach) muscle.
Saline	A solution of sodium chloride (salt) and water.
Seroma	Localized collection of serum (the watery portion of blood), that resembles a tumor.
Serratus	Muscle located beneath the chest's pectoralis major and minor muscles and the rib cage.
Silicone Elastomer	A type of silicone that has elastic properties similar to rubber.
Subglandular Placement	Placement of the breast implant behind the skin and mammary gland, but on top of the chest (pectoralis) muscle. Also called prepectoral or retromammary placement.
Submuscular Placement	Placement of the breast implant under the chest (pectoralis) muscle, or under the pectoralis and serratus muscles. Also called retropectoral or subpectoral placement.
Surgical Incision	Cut made in tissue for surgical purposes.
Transaxillary Incision	Incision across the long axis of the armpit (axilla).
Umbilical	Relating to the belly button.
Unilateral	Affecting only left or right breast.

M558 (*Draft 27-July-04*)

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